AMENDMENTS TO THE SPECIFICATION

Please replace paragraph [0029] with the following amended paragraph:

[0029] FIG. 1A depicts an embodiment of a fully integrated iontophoretic patch device for body decoration according to the present invention. FIG. 1A shows a cross-sectional view of the patch of FIG. 1B along line A-A. In this embodiment, patch 100 may comprise first electrode 110(1), identified as "cathode," second electrode 110(2), identified as "anode," and electrochemical cell 130 as the power supply of patch 100. Patch 100 may also comprise conductive layer 140 to provide an interfacing layer between patch 100 and a body area of a subject. Patch 100 may also comprise conductive layer 120, which in FIG. 1A ~~FIG 1A~~ includes color formulation 125 ~~formulation125~~, and which is preferably a conductive composition to provide dyes and/or pigments to a desired body area for the decoration. Optionally, patch 100 also comprises a decorative template 150 to provide the decorative form to be made on the body area. In a preferred embodiment as shown in FIG. 1A ~~FIG 1A~~, the electrodes, conductive layer, color formulation, and electrochemical cell may be supported on substrate 160. Electrochemical cell 130 may optionally be disposed on substrate 160, electrode 110(2) disposed on electrochemical cell 130, and conductive layer 140 disposed on electrode 110(2). Electrode 110(1) may be disposed on substrate 160 in spaced relation to electrochemical cell 130 and electrode 110(2) to define a gap between the two electrodes. Conductive layer 120 including color formulation 125 may be disposed on electrode 110(1) and decorative template 150 disposed on conductive layer 120 including color formulation 125. In an alternative embodiment, patch 100 does not include conductive layer 120 (or conductive layer 140). In this alternative embodiment color formulation 125 is accommodated in a chamber (not shown in figure) attached to electrode 110(1). Color formulation is then applied without conductive fluid onto decorative template 150 to form desired body decoration.

Please replace paragraph [0040] with the following amended paragraph:

[0040] Cathode and anode electrodes 110(1) and 110(2) are preferably composed of a conductive material. In a preferred embodiment, at least one of the electrodes may comprise silver metal. In a further preferred embodiment, at least one electrode may comprise both silver and silver

chloride. Yet, in other preferred embodiments, at least one of the electrodes may comprise carbon or zinc. Alternatively, at least one of the electrodes may comprise graphite or platinum. Any other conductive element or compound, including metal and non-metal materials, can be used as electrode materials. The electrodes may be either provided as thin sheets, linked to the power source, or printed onto a substrate in spaced relation to each other to define a gap therebetween. The electrode area can be continuous, or formed as a drawing, in any shape, to provide a decorative form. Optionally, patch 100 can include a plurality of anodes and a plurality of cathodes. Such a multi-electrode patch facilitates providing simultaneously a plurality of body decorations in different body areas.

Please replace paragraph [0061] with the following amended paragraph:

[0061] In a preferred embodiment, dyes and pigments may be such that they adhere to body outer tissue, in order to provide a prolonged retention of the decoration in the body. The adherence may be based on either chemical bonding to tissue materials, such as proteins, glycoproteins, glycolipids, ~~polysecharides~~ polysaccharides and the like; by physical forces of adherence; by binding to keratin filaments; or by solubilization in an intercellular space or in a body cell.

Please replace paragraph [0093] with the following amended paragraph:

[0093] In this assay the experiment format was changed. Instead of dye solution ~~we have used~~ dry dye with conductive gel was used. 200 µl ~~□l~~ of 40 mg/ml FD&C Blue no.1 (dissolved in ethanol +20% ddw) was added to the donor chambers and was allowed to dry on the skin. 1-2 hours later, 1 ml of gel containing 39.2g ddw, 0.4g Hydroxyethyl cellulose (Natrosal) and 0.4g NaCl was added to the chambers and the penetration of the dye into the skin was assayed with and without electrical current (the current was unlimited). The assay lasted 30 minutes and was done in duplicates. The dye penetration depth was determined by tape stripping.

Please replace paragraph [0095] with the following amended paragraph:

[0095] The skin penetration of the blue color mixture was tested under the same conditions as in the ~~pervious~~ previous assay. 200 μl of the blue color mixture (dissolved in 100% ethanol) was added to the donor chambers and was allowed to dry on the skin. 1-2 hours later, 1 ml of gel containing 39.2g ddw and 0.4g Hydroxyethyl cellulose (Natrosol; without NaCl) was added to the donor chambers and the penetration of the dye into the skin was assayed with and without electrical current (the current was unlimited). The assay lasted 30 minutes and was done in duplicates. The dye penetration depth was determined by tape stripping.

Please replace paragraphs [0097] – [0100] with the following amended paragraphs:

[0097] To improve the skin penetration of FD&C Blue no.1, the Stratum Corneum was removed by repeated adhesive tape stripping (15 strips were removed). Other parameters were the same as described in Experiment 1.4 ~~the fourth assay~~.

[0098] In this assay, prior to the experiment the Stratum Corneum lipid content was reduced by cleaning the skin with Acetone. The skin penetration of FD&C Blue no.1 was then tested under the same conditions as in Experiment 1.4 ~~the fourth assay~~.

[0099] The skin penetration of 20 mg/ml FD&C Yellow no.6 and 20 mg/ml FD&C Red no. 40 was tested using skin that was cleaned with 70% ethanol. 200 μl ~~□l~~ of each dye (dissolved in ethanol + 30% ddw) was added to the donor chambers and was allowed to dry on the skin. 1-2 hours later, 1 ml of gel containing 39.2g ddw and 0.4g Hydroxyethyl cellulose (Natrosol; without NaCl) was added to the donor chambers and the penetration of the dyes into the skin was assayed with and without electrical current (the current was unlimited). The assay lasted 30 minutes and was done in duplicates. The dye penetration depth was determined by tape stripping.

[0100] The skin penetration of 20 mg/ml FD&C Yellow no.6 was tested under the same conditions as in the previous ~~pervious~~ assay except for the current that was limited to 335 mA (500 $\mu A/cm^2$).

Please replace paragraph [0102] with the following amended paragraph:

[0102] To make the tattooing procedure more suitable for home consumers, in this assay ~~we tested~~ the ability of FD&C Red no. 40 to penetrate into skin that was cleaned with 10% lactic acid was tested. 10% lactic acid, pH> 3.5 is known to be used for home peeling (approved by FDA). Prior to the assay the skin was cleaned with 10% lactic acid pH= 3.5-4. 200 :l of 20 mg/ml FD&C Red no. 40 (dissolved in ethanol + 30% ddw) was added to the donor chambers and was allowed to dry on the skin. 1-2 hours later, 1 ml of gel containing 39.2g ddw and 0.4g Hydroxyethyl cellulose (Natrosal; without NaCl) was added to the donor chambers and the penetration of the dyes into the skin was assayed with and without electrical current (the current was limited to 335 mA). The assay lasted 30 minutes and was done in duplicates. The dye penetration depth was determined by tape stripping.

Please replace paragraphs [0104] and [0105] with the following amended paragraphs:

[104] To improve the dye uniformity in the present assay we have used hydrogel instead of conductive gel. Prior to the assay the Stratum Corneum was removed by repeated adhesive tape stripping (15 strips were removed). 200 µl ~~□l~~ of 20 mg/ml FD&C Red no. 40 (dissolved in ethanol + 30% ddw) was added to the donor chambers and was allowed to dry on the skin. 1-2 hours later, pieces of hydrogel were placed in the donor chambers, on top of the dried dyes, and the penetration of the dyes into the skin was assayed with and without electrical current (the current was limited to 335 mA). In the active experiments, the cathode/anode were attached to the Ag/AgCl wires that were inserted into the chamber cells, touching the hydrogel. The assay lasted 30 minutes and was done in duplicates. The dye penetration depth was determined by tape stripping. Seven minutes after the beginning of the assay the charge rose to 8V to achieve the desirable current of 0.335 mA. ~~To reduce the voltage, it~~ The voltage was limited to 3V after 7 minutes ~~from this minute and~~ until the end of the assay.

[0105] Table 2 shows the results of Experiments 1.1-1.13. According to the results, dye penetration into the skin with dyeing uniformity can be achieve by using, but not limited to, the following parameters: removing the stratum corneum by using tap strips or cleaning the skin with 10% lactic acid (pH > 3.5); using dried color with conductive gel, preferably hydrogel; and

placing the dyes under ~~udner~~ the correct electrode, depending on the dye charge. According to the results, the dye penetration into the skin occurred when dried color with conductive gel or hydrogel were used, as in Experiments 1.4-1.13. Hydrogel improved dyeing uniformity, as in Experiment 1.13 compared to Experiment 1.10. The dye penetration was increased and dyeing uniformity improved by removing the Stratum Corneum, as in Experiments 1.6 and 1.10. Cleaning the skin with acetone or ethanol had only slight impact on the dye penetration depth and dyeing uniformity as indicated by tape stripping, as in Experiment 1.11. Red and yellow dyes penetrated the skin more easily than blue dye, which may be attributable to the lower molecular weight of the red and yellow dyes compared to the blue dye. Thus, embodiments of the present invention may be used for body decoration.

Please replace paragraphs [0115] – [0117] with the following amended paragraphs:

[0115] FIGS. 11A and 11B show the blue heart-shaped tattoos created with high concentration ink on stretched skin to simulate the skin on the subject's body area. FIG. 11A shows the blue heart-shaped tattoos created with the high concentration ~~highconcentration~~ ink on pretreated stretched skin and with application of electric current. FIG. 11B shows the blue heart-shaped tattoos created with the high concentration ink on pretreated skin without application of electric current. The stretched skin provided acceptable ink penetration depth and improved tattoo visibility, as compared to the tattoos in Experiment 2.5.

[0116] The skin penetration of 2 mg/ml Indocyanine green in ethanol with 40% ddw was assayed using the vertical diffusion cells. 200 µl of the dye was added to the donor chambers and was allowed to dry on the skin. One or two hours later, 1 ml of gel containing 39.2g ddw and 0.4g Hydroxyethyl cellulose (Natrosol) was added to the donor chambers with (active assay) and without (passive assay) electric current. In the active experiments, Ag/AgCl wires were inserted into the chamber cells and the cathode/anode were attached to them. The required current was 500 $\mu A/cm^2$ ~~µA/cm2~~, thus the power supply was accordingly tuned to 320 µA (for 0.64 cm^2). Prior to the assay, the skin was cleaned with 10% lactic acid of pH≅3.5. The assay lasted 30 minutes and was done in duplicates. The dye penetration depth was determined by tape stripping.

[0117] Blue heart-shaped tattoos were created, as described before in <u>Experiment 2.6</u> ~~Experiment 6~~. This experiment was conducted to sharpen the tattoo by soaking the hydrogel in ddw for only few seconds. FIG. 12A shows the blue heart-shaped tattoos created with the ddw-soaked hydrogel and application of electric current. FIG. 12B shows the blue heart-shaped tattoos created with the ddw-soaked hydrogel and without application of electric current. These tattoos were sharper than those of Experiment 2.6 that did not use ddw-soaked hydrogel.

Please replace paragraph [0120] with the following amended paragraph:

[0120]To increase the blue heart-shaped penetration depth, 200 mg/ml Blue V (in ddw with 20% ethanol) was used. The assay lasted 20 minutes to avoid decrease in the current due to increase in the voltage. Other parameters were the same as described in <u>Experiment 2.6</u> ~~Experiment 6~~. Instead of using tape stripping to determine the dye penetration depth, the skin was washed with tap water to determine the dye's water durability. Washing the skin removed almost all the dye.

Please replace paragraph [0126] with the following amended paragraph:

[0126] Table 3 shows the results of Experiments 2.1-2.16. According to the results, iontophoresis increased the skin penetration depth of Blue V under the cathode electrode, as indicated in Experiment 2.1 and FIG. 6. Using embodiments of the present invention, tattoos were successfully created on a body area by imprinting the decorative form on the hydrogel, using either tissue papers or polyesters as templates. Cleaning the skin with 10% lactic acid (pH $\cong$ 3.5) strengthened the skin dyeing, as indicated in Experiment 2.4 compared to Experiment 2.3 and FIG. 8 compared to FIG. 7. Increasing the dye concentration contributed to increased penetration depth for some dyes, as indicated in Experiment 2.5 compared to Experiment 2.4 and FIG. 10 compared to FIG. 8. The heart shape imprint was less sharp in the petri dish model (as indicated in Experiment 2.6 compared with Experiment 2.5, which apparently was because the skins in this model were not stretched. The penetration depth of indocyanine green was not affected by iontophoresis, as indicated by Experiments 2.7 and 2.10. Adding water to the hydrogel had a negative effect on the tattoo imprint sharpness, as indicated in Experiment 2.6 compared with Experiment 2.8. Longer iontophoretic application prolonged the tattoo life span, as indicated in Experiment 2.15 compared to Experiment 2.9. Adding the polyester template that

concentrated the current flow through the imprint area prolonged the tattoo life span, as indicated in Experiment 2.16 ~~Experiment 16~~. Finally, the hydrogel with the polyester on it was less adhesive, and thus the tattoo formed using this arrangement was slightly blurred. (*See* FIG. 14.) Thus, embodiments of the present invention may be used for body decoration.